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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/010,304
Filing Date	11/08/2001
First Named Inventor	Ringeisen, Timothy
Art Unit	1615
Examiner Name	Silverman, Eric E.
Attorney Docket Number	KN P-0020

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☑ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  (1) Certificate of Mailing
  (2) Return Receipt Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	c/o Kensey Nash Corporation		
Signature	Jeffrey R. Ramberg		
Printed name	Jeffrey R. Ramberg		
Date	07/14/2006	Reg. No.	34,700

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Jeffrey R. Ramberg		
Typed or printed name	Jeffrey R. Ramberg	Date	07/14/2006

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTN: OFFICE OF THE DEPUTY COMMISSIONER FOR PATENT EXAMINATION POLICY

Applicant:	Ringeisen, T.	Group Art Unit:	1615
Serial No.:	10/010,304	Examiner:	Silverman, Eric
Filing Date:	November 8, 2001	Atty. Docket No.:	KN P-0020

For: Method for Making a Porous Polymeric Material

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Certificate of Mailing Under 37 CFR §1.8

I hereby certify that the following correspondence is being deposited on the date shown below as first class mail in an envelope addressed to: *Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450:*

Petition Under 37 C.F.R. §1.181 to Invoke the Supervisory Authority of the Commissioner

Transmittal

Return Receipt Postcard

7-14-2006
Date

Jeffrey R Ramberg
Signature

Jeffrey R. Ramberg
Typed or printed name of person signing Certificate

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTN: OFFICE OF THE DEPUTY COMMISSIONER FOR PATENT EXAMINATION POLICY

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For: Method for Making a Porous Polymeric Material

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. §1.181

Dear Sir:

Pursuant to 37 C.F.R. §1.181 and MPEP §1002.02(b), Applicant petitions the Office of the Deputy Commissioner for Patent Examination Policy to invoke the supervisory authority of the Commissioner. Specifically, Applicant respectfully requests the Deputy Commissioner compel the examiner in charge of the instant application to follow the procedures stated in MPEP §706.04 regarding the issue of a new rejection of claims previously indicated as allowable.

STATEMENT OF FACTS

In a previous office action dated August 10, 2005 (the "August Action", which is enclosed as Appendix A), Primary Examiner James M. Spear of Art Unit 1618 had indicated that claims

6-10, 14, 18-24, and 28 "are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." This language can be found in the MPEP §707.07(j) as Form Paragraph 7.43, and is to be used in situations "[w]here the examiner is satisfied that the prior art has been fully developed and some of the claims are clearly allowable". Furthermore, the use of the Form Paragraph 7.43 "may be used to indicate allowable subject matter" of claims that are otherwise objected to.

In reliance upon Primary Examiner Spear's indication of conditionally allowable subject matter, Applicant's response of November 10, 2005 (enclosed as Appendix B) amended claims 6-9, 14, 18-23, and 28, converting such claims into independent claims as suggested--that is, including all of the limitations of the respective base claims and any intervening claims. Additionally, to overcome the rejections to the balance of the claims, Applicant cancelled claims 1-5, 11-13, 15-17, 25-27 and 29-32 in order to advance the prosecution, and put the amended claims in condition for allowance.

Following the August Action, the case was passed to Examiner Eric Silverman in Art Unit 1615, who issued a new rejection on 1/13/2006 (the January Action, enclosed as Appendix C) in response to Applicant's reply to Primary Examiner Spear's August Action. Nothing was noted with regard to the previous rejection, or about the ostensibly allowable claims. Furthermore, no new art was cited.

The MPEP gives guidance in §706.04 for a situation where there has been an indication of allowable subject matter, and where there has been previous action by a different examiner:

> *"Full faith and credit should be given to the search and action of a previous examiner unless there is a clear error in the previous action or knowledge of other prior art. In general, an examiner should not take an entirely new approach or attempt to reorient the point of view of a previous examiner, or make a new search in the mere hope of finding something. (citing Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 139, 57 USPQ2d 1449, 1499-50 (D. Mass. 2001).)"*

In the unusual instance that it is necessary to reject a previously allowed claim, the MPEP in §706.04, further provides language to the examiner in which he is to point out in the office action that the claim now being rejected was previously allowed. This can be found in Form Paragraph 7.50:

> *"The indicated allowability of claim **[ ]** is withdrawn in view of the newly discovered reference(s) to **[new reference(s)]**. Rejection(s) based on the newly cited reference(s) follow."*

Form Paragraph 7.50 seemingly requires "newly discovered references" for rejecting claims that a previous examiner had indicated as being allowable. A review of the Image File Wrapper for the present application reveals that Examiner Silverman updated the search on 1/4/2006; however no new references were cited, in fact, no new references are listed in either the search notes or the subsequent notice of references cited. The existing five references were cited in the pending case prior to the August Action, and were previously considered by Primary Examiner Spear.

As a result of the January Action, the pending claims stand rejected by Examiner Silverman, without addressing the previous indication of conditionally allowable claims, and furthermore without addressing the fact that Applicant performed the amendments suggested by Primary Examiner Spear, which seemingly would have converted allowable claims into allowed claims. Further, there was no citation by Examiner Silverman of newly discovered references.

No new references have been cited, and no new combinations of existing references have been applied; additionally, no new claims have been rejected. In other words, the only claims that have been rejected in the present Action (by the same references and same combinations of references), are those that were rejected several Office Actions ago, and have since been argued and/or amended to overcome the earlier rejections.

In conclusion, and as stated at MPEP §706.04:

> *"A claim noted as allowable shall thereafter be rejected only after the proposed rejection has been submitted to the primary examiner for consideration of all the facts and approval of the proposed action. Great care should be exercised in authorizing such a rejection. See Ex parte Grier, 1923 C.D. 27, 309 O.G. 223 (Comm'r Pat. 1923); Ex parte Hay, 1909 C.D. 18, 139 O.G. 197 (Comm'r Pat. 1909)."*

There is no indication in the January Action that any of these actions took place.

CONCLUSION

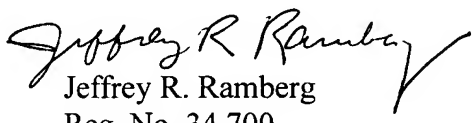
Claims 6-10, 14, 18-24 and 28, were previously identified by Primary Examiner Spear as containing allowable subject matter. Applicant respectfully submits that Primary Examiner Spear's objections to those claims were rectified in Applicant's response dated 11/15/05.

In view of the above facts, Applicants respectfully request that the Deputy Commissioner instruct the examiner in charge of the instant application to issue a Notice of Allowance directed to claims 6-10, 14, 18-24 and 28. In the alternative, Applicant respectfully requests that the Deputy Commissioner instruct the examiner to comply with MPEP §706.04, if he believes that previously allowable claims are to be rejected. In doing so he should either: provide Applicant with the newly cited reference(s) in accordance with Form Paragraph 7.50, or submit an indication of clean error by Examiner Spear, with an explanation of same.

Applicant believes that no fee is due in connection with this petition. If this turns out to be incorrect, the Finance Division is authorized to debit any deficiency to the undersigned attorney's Deposit Account No. 50-1020.

Should the Patent Office have any questions concerning this submission, or deem that any further action on Applicant's part would be desirable, the Office is invited to telephone Applicant's undersigned representative.

Respectfully submitted,



Jeffrey R. Ramberg
Reg. No. 34,700

July 13, 2006

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Enclosures: Appendix A: Office Action of August 10, 2005
Appendix B: Applicant's reply of November 10, 2005
Appendix C: Office Action of January 13, 2006

APPENDIX A

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,304	11/08/2001	Timothy Ringeisen	KN P-0020	5717

7590 08/10/2005

Jeffrey C. Kelly, Esq.
Kensey Nash Corporation
55 East Uwchlan Avenue
Exton, PA 19341

EXAMINER	
SPEAR, JAMES M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,304	RINGEISEN, TIMOTHY	
	Examiner	Art Unit	
	James M. Spear	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 January 1932*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11-13,15-17,25-27 and 29-32* is/are rejected.

7)☒ Claim(s) *6-10,14,18-24 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear

JAMES M. SPEAR
PRIMARY EXAMINER
AU 1618

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Request For Continued Examination and Amendment filed 08 October 2004 have been entered.

1. Claims 13, 14, 27 and 28 are objected to because of the following informalities: The claims recite improper terminology, "selected from the group comprising", rather than proper Markush Language, "selected from the group consisting of". See MPEP 2173.05(h). MARKUSH GROUPS. Appropriate correction is required.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-3, 5, 11-13, 15, 17, 25-27, 29, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Reischl et al US 3,553,008.

4. Claims 1, 2, 4, 12, 15-17, 25, 26, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Einstman US 3,492,154.

The claims are rejected for the reasons set forth in the prior office action mailed 05 April 2004 and Advisory Action mailed 22 September 2004.

5. Applicant's arguments filed 08 October 2004 have been fully considered but they are not persuasive. The Declaration filed 09 June 2004

has been considered. Applicant argues that , "One of the differences is that the liquids of Einstman and Reischl do not cause gelling of the entire volume of solution as do the claimed second solvents". "This is an inherent characteristic of the claimed second solvent that causes the solution to thicken to a gel and it is expressly stated as such, for example, at page 4, lines 39-41." "Thus the liquids of Einstman and Reischl that cause gelation are not the same as the claimed second solvents of Applicant." "As the Declaration point out, these liquids are non-solvent or failed solvents." It is the position of this office that while applicant's arguments relate to different terminology the prior art clearly shows the process of applicant's claims. Einstman teaches a process wherein a first and second solvent are utilized to formulate a porous polymeric body that may be characterized by different shapes. Applicant's independent claims are not limited to particular polymer or solvent combinations. The resulting products of the prior include biological membranes. Einstman, Column 1, lines 33-41, column 5. These products would inherently have the same properties as applicant's polymeric bodies. When the second solvent is added there is a change is viscosity of the overall composition irrespective of what

specifically is formed as in applicants steps e, & f, claim 1. The scope of applicant's claims read on the prior art of record.

It would appear that contrary to applicant's arguments Reischl et al does cause gelation of the entire volume of solution. See column 1, lines 45-61. The solvent is present in an amount to gel the polyurethane solution. One skilled in the art would immediately envision conventional means for utilizing the polymeric bodies formed. For example Reischl et al teaches utilizing a substrate in forming the different shaped bodies. Column 1, line 62 through column 2, line 3.

6. Claims 6-10, 14, 18-24 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-5, 11-13, 15-17, 25-27 and 29-32 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone

number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James M. Spear

James M Spear
Primary Examiner
Art Unit 1618

August 8, 2005

APPENDIX B

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Ringeisen, T.	Group Art Unit:	1618
Serial No.:	10/010,304	Examiner:	Spear, James M.
Filing Date:	November 8, 2001	Atty. Docket No.:	KN P-0020
For:	Method for Making a Porous Polymeric Material		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT IN REPLY TO FIFTH OFFICE ACTION

Dear Sir:

In regard to the Office Action dated August 10, 2005, please amend the application as follows:

Please enter the **Amendments to the Claims,** which are reflected in the listing of claims, which begins on page 2 of this paper. The specific changes are indicated by underscoring text to be added, and by ~~striking through~~ or [[double bracketing]] text to be deleted.

Applicant's **Remarks** begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

The following listing of claims contains all claims that are, or ever were, in the present patent application. This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of claims:

1-5 (canceled).

6 (currently amended). ~~The process of claim 1~~ A process for creating a porous polymeric body of desired shape, comprising the steps of:

a. selecting a polymer;

b. identifying a first solvent that is capable of substantially dissolving a solid form of the polymer;

c. identifying a second solvent that does not substantially dissolve the polymer in solid form, but instead merely swells the solid polymer;

d. providing at least sufficient first solvent to said polymer as to substantially dissolve the polymer in the first solvent to form a solution;

e. adding a quantity of the second solvent to the solution, whereupon an entire volume of the solution begins to gel;

f. continuing the adding of the second solvent until a viscosity of the gel increases to a point where the gel is suitable for shape-forming;

g. shape-forming the gel; and

h. removing the first and second solvents from the gel, wherein a biologically active agent is mixed with the polymer and first solvent prior to addition of the second solvent.

7 (currently amended). ~~The process of claim 1~~ A process for creating a porous polymeric body of desired shape, comprising the steps of:

a. selecting a polymer;

b. identifying a first solvent that is capable of substantially dissolving a solid form of the polymer;

c. identifying a second solvent that does not substantially dissolve the polymer in solid form, but instead merely swells the solid polymer;

d. providing at least sufficient first solvent to said polymer as to substantially dissolve the polymer in the first solvent to form a solution;

e. adding a quantity of the second solvent to the solution, whereupon an entire volume of the solution begins to gel;

f. continuing the adding of the second solvent until a viscosity of the gel increases to a point where the gel is suitable for shape-forming;

g. shape-forming the gel; and

h. removing the first and second solvents from the gel, wherein a biologically active agent is mixed with the second solvent prior to addition to the first solvent/polymer solution.

8 (currently amended). ~~The process of claim 1~~ A process for creating a porous polymeric body of desired shape, comprising the steps of:

a. selecting a polymer;

b. identifying a first solvent that is capable of substantially dissolving a solid form of the polymer;

c. identifying a second solvent that does not substantially dissolve the polymer in solid form, but instead merely swells the solid polymer;

d. providing at least sufficient first solvent to said polymer as to substantially dissolve the polymer in the first solvent to form a solution;

e. adding a quantity of the second solvent to the solution, whereupon an entire volume of the solution begins to gel;

f. continuing the adding of the second solvent until a viscosity of the gel increases to a point where the gel is suitable for shape-forming;

g. shape-forming the gel; and

h. removing the first and second solvents from the gel, wherein a biologically active agent is mixed with the gel prior to removal of the first and second solvents.

9 (currently amended). ~~The process of claim 1~~ A process for creating a porous polymeric body of desired shape, comprising the steps of:

a. selecting a polymer;

b. identifying a first solvent that is capable of substantially dissolving a solid form of the polymer;

c. identifying a second solvent that does not substantially dissolve the polymer in solid form, but instead merely swells the solid polymer;

d. providing at least sufficient first solvent to said polymer as to substantially dissolve the polymer in the first solvent to form a solution;

e. adding a quantity of the second solvent to the solution, whereupon an entire volume of the solution begins to gel;

f. continuing the adding of the second solvent until a viscosity of the gel increases to a point where the gel is suitable for shape-forming;

g. shape-forming the gel; and

h. removing the first and second solvents from the gel, wherein a biologically active agent is incorporated within the pores of the polymeric body after removal of the first and second solvent.

10 (Original). The process of any of claims 6, 7, 8 or 9, wherein the biologically active agent is selected from one or more of the following: physiologically acceptable drugs, surfactants, ceramics, hydroxyapatites, tricalciumphosphates, antithrombogenic agents, antibiotics, biologic modifiers, glycosaminoglycans, proteins, hormones, antigens, viruses, cells or cellular components.

11-13 (canceled).

14 (currently amended). ~~The process of claim 12,~~ A process for creating a porous polymeric body of desired shape, comprising the steps of:

a. selecting a polymer;

b. identifying a first solvent that is capable of substantially dissolving a solid form of the polymer;

c. identifying a second solvent that does not substantially dissolve the polymer in solid form, but instead merely swells the solid polymer;

d. providing at least sufficient first solvent to said polymer as to substantially dissolve the polymer in the first solvent to form a solution;

e. adding a quantity of the second solvent to the solution, whereupon an entire volume of the solution begins to gel;

f. continuing the adding of the second solvent until a viscosity of the gel increases to a point where the gel is suitable for shape-forming;

g. shape-forming the gel; and

h. removing the first and second solvents from the gel, wherein the polymer comprises a polyurethane, and further wherein the first solvent comprises tetrahydrofuran, and the second solvent comprises at least one solvent selected from the group ~~comprising~~ consisting of p-dioxane, dimethyl sulfoxide and o-xylene.

15-17 (canceled).

18 (currently amended). ~~The process of claim 17,~~ A process for creating a composite body comprising a porous polymeric body using a gel enhanced phase separation technique, the process comprising the steps of:

a. substantially dissolving a selected polymer in a suitable first organic solvent to form a solution;

b. adding a suitable second solvent to the solution that causes an entire volume of the solvent/polymer solution to thicken into a gel;

c. placing the gel in contact with at least one other material; and

d. removing the first and second solvent, thereby leaving a porous polymer and the at least one other material, wherein said porous polymer and said at least one other material are mechanically bound to each other, wherein the other material provides reinforcement to the porous polymer, and further wherein the other material is in the form of reinforcing threads.

19 (currently amended). ~~The process of claim 15~~ A process for creating a composite body comprising a porous polymeric body using a gel enhanced phase separation technique, the process comprising the steps of:

a. substantially dissolving a selected polymer in a suitable first organic solvent to form a solution;

b. adding a suitable second solvent to the solution that causes an entire volume of the solvent/polymer solution to thicken into a gel;

c. placing the gel in contact with at least one other material; and

d. removing the first and second solvent, thereby leaving a porous polymer and the at least one other material, wherein said porous polymer and said at least one other material are mechanically bound to each other, wherein the other material is in the form of reinforcing rings.

Claim 20 (currently amended): ~~The process of claim 16~~ A process for creating a composite body comprising a porous polymeric body using a gel enhanced phase separation technique, the process comprising the steps of:

a. substantially dissolving a selected polymer in a suitable first organic solvent to form a solution;

b. adding a suitable second solvent to the solution that causes an entire volume of the solvent/polymer solution to thicken into a gel;

c. placing the gel in contact with at least one other material; and

d. removing the first and second solvent, thereby leaving a porous polymer and the at least one other material, wherein said porous polymer and said at least one other material are mechanically bound to each other, wherein the porous polymeric body comprises a prosthesis, and further wherein said other material aids in attaching the prosthesis to host tissue.

21 (currently amended). ~~The process of claim 15,~~ A process for creating a composite body comprising a porous polymeric body using a gel enhanced phase separation technique, the process comprising the steps of:

a. substantially dissolving a selected polymer in a suitable first organic solvent to form a solution;

b. adding a suitable second solvent to the solution that causes an entire volume of the solvent/polymer solution to thicken into a gel;

c. placing the gel in contact with at least one other material; and

d. removing the first and second solvent, thereby leaving a porous polymer and the at least one other material, wherein said porous polymer and said at least one other material are mechanically bound to each other, wherein the other material is biodegradable, and further wherein the other material is in the form of a suture.

22 (currently amended). ~~The process of claim 15,~~ A process for creating a composite body comprising a porous polymeric body using a gel enhanced phase separation technique, the process comprising the steps of:

a. substantially dissolving a selected polymer in a suitable first organic solvent to form a solution;

b. adding a suitable second solvent to the solution that causes an entire volume of the solvent/polymer solution to thicken into a gel;

c. placing the gel in contact with at least one other material; and

d. removing the first and second solvent, thereby leaving a porous polymer and the at least one other material, wherein said porous polymer and said at least one other material are mechanically bound to each other, wherein the other material is biodegradable, and further wherein the other material is in the form of a tack.

23 (currently amended). ~~The process of claim 16~~ A process for creating a composite body comprising a porous polymeric body using a gel enhanced phase separation technique, the process comprising the steps of:

a. substantially dissolving a selected polymer in a suitable first organic solvent to form a solution;

b. adding a suitable second solvent to the solution that causes an entire volume of the solvent/polymer solution to thicken into a gel;

c. placing the gel in contact with at least one other material; and

d. removing the first and second solvent, thereby leaving a porous polymer and the at least one other material, wherein said porous polymer and said at least one other material are mechanically bound to each other, wherein the other material is a biologically active agent.

24 (Original). The process of claim 23, wherein the biologically active agent is selected from one or more of the following: physiologically acceptable drugs, surfactants, ceramics, hydroxyapatites, tricalciumphosphates, antithrombogenic agents, antibiotics, biologic modifiers, glycosaminoglycans, proteins, hormones, antigens, viruses, cells or cellular components.

25-27 (canceled).

28 (currently amended). ~~The process of claim 26,~~ A process for creating a composite body comprising a porous polymeric body using a gel enhanced phase separation technique, the process comprising the steps of:

a. substantially dissolving a selected polymer in a suitable first organic solvent to form a solution;

b. adding a suitable second solvent to the solution that causes an entire volume of the solvent/polymer solution to thicken into a gel;

c. placing the gel in contact with at least one other material; and

d. removing the first and second solvent, thereby leaving a porous polymer and the at least one other material, wherein said porous polymer and said at least one other material are mechanically bound to each other, wherein the selected polymer comprises a polyurethane, and further wherein the first solvent comprises tetrahydrofuran, and the second solvent comprises at least one solvent selected from the group ~~comprising~~ consisting of p-dioxane, dimethyl sulfoxide and o-xylene.

29-32 (canceled).

REMARKS

Claims 1-32 are pending. Of these, claims 1-5, 11-13, 15-17, 25-27 and 29-32 are rejected. Claims 6-10, 14, 18-24 and 28 are conditionally allowable. Claims 6-9, 14, 18-23 and 28 have been amended. Claims 1-5, 11-13, 15-17, 25-27 and 29-32 have been canceled without prejudice or disclaimer to the subject matter that was claimed therein. Applicant reserves the right to pursue one or more of the canceled claims in a Continuing application.

Applicant respectfully submits that the instant claim amendments add no new matter to the application. Instead, the amendments merely rewrite dependent claims in independent form, or address formalities such as proper terminology or format.

Claim Objections

Claims 13, 14, 27 and 28 are objected to on grounds that the claims recite improper Markush terminology. Applicants respectfully submit that cancellation of claims 13 and 27, and amendment of claims 14 and 28 now renders this objection as moot.

The Prior Art Rejections

Claims 1-3, 5, 11-13, 15, 17, 25-27, 29, 30 and 32 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,553,008 to Reischl et al. (hereinafter referred to as "Reischl"). Claims 1, 2, 4, 12, 15-17, 25, 26, 29 and 31 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,492,154 to Einstman (hereinafter referred to as "Einstman"). The claims were rejected for the reasons of record set forth in the prior Office Action mailed 05 April 2004 and Advisory Action mailed 22 September 2004.

Applicant respectfully submits that the instant amendments render these rejections moot. Specifically, the Action stated that claims 6-10, 14, 18-24 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant has now amended these allowable dependent claims accordingly.

In view of the amendments and the above remarks, Applicant respectfully submits that the present application is in condition for allowance. Accordingly, Applicant respectfully requests issuance of a Notice of Allowance directed to claims 6-10, 14, 18-24 and 28.

Should the Examiner deem that any further action on the part of Applicant would be desirable, the Examiner is invited to telephone Applicant's undersigned representative.

Respectfully submitted,

Jeffrey R. Ramberg
Reg. No. 34,700

November 10, 2005

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Exton, PA 19341
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PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 12

Application Number	10/010,304
Filing Date	11/08/2001
First Named Inventor	Ringeisen, Timothy A.
Art Unit	1618
Examiner Name	Spear, James M.
Attorney Docket Number	KN P-0020

ENCLOSURES *(Check all that apply)*

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [x] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation
- [ ] Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please identify below):
  - (1) Certificate of Mailing
  - (2) Return Receipt Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	c/o Kensey Nash Corporation		
Signature	Jeffrey R Ramberg		
Printed name	Jeffrey R. Ramberg		
Date	11/10/2005	Reg. No.	34,700

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Jeffrey R Ramberg		
Typed or printed name	Jeffrey R. Ramberg	Date	11/10/2005

PTO/SB/17 (12-04v2)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($)	900.00

Complete if Known	
Application Number	10/010,304
Filing Date	Nov 8, 2001
First Named Inventor	Timothy A. Ringeisen
Examiner Name	James M. Spear
Art Unit	1648
Attorney Docket No.	KN P 0020

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 50-1671 Deposit Account Name: Kensey Nash Corporation

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☑ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☐ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☑ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	0.00
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims		Fee ($)		Fee Paid ($)
_____	- 20 or HP =	_____	x	_____	=	0.00

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		Extra Claims		Fee ($)		Fee Paid ($)
12	- 3 or HP =	9	x	100.00	=	900.00

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims Fee ($)	Fee Paid ($)
_____	0.00

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof	Fee ($)		Fee Paid ($)
_____	- 100 =	_____	/ 50 =	_____ (round up to a whole number)	_____	=	0.00

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): _____	

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	Telephone 610-5944392
Name (Print/Type)	Jeffrey C. Kelly		Date 11/10/05

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Ringeisen, T.	Group Art Unit:	1618
Serial No.:	10/010,304	Examiner:	Young, Micah-Paul
Filing Date:	November 8, 2001	Atty. Docket No.:	KN P-0020
For:	Method for Making a Porous Polymeric Material		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Certificate of Mailing Under 37 CFR §1.8

I hereby certify that the following correspondence is being deposited on the date shown below as first class mail in an envelope addressed to: *Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450*

Amendment in Reply to Fifth Office Action

Transmittal

Fee Transmittal

Return Receipt Postcard

Nov. 10, 2005
Date

Jeffrey R Ramberg
Signature

Jeffrey R. Ramberg
Typed or printed name of person signing Certificate

APPENDIX C

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,304	11/08/2001	Timothy Ringeisen	KN P-0020	5717

7590 01/13/2006

Jeffrey C. Kelly, Esq.
Kensey Nash Corporation
55 East Uwchlan Avenue
Exton, PA 19341

EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,304	RINGEISEN, TIMOTHY	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 – 14, 16 – 24, and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 – 14, 16 – 24, and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant is advised that the Examiner and Art Unit to which this Application is assigned have changed. The Art Unit to which this application is currently assigned is **Art Unit** 1615, and the Examiner to which this application is currently assigned is **Eric E. Silverman, PhD**, whose contact information can be found at the end of this action.

Receipt of Amendment, remarks and arguments attached thereto, filed 11/15/05, is acknowledged.

In amendment, Claims 1 – 5, 15 – 17, 25 – 27, and 29 – 32 were cancelled and the remaining claims were amended. Accordingly, claims 6 – 14, 16 – 24, and 28 are pending in this action.

Claim Objections

Response to Arguments

The amendment filed 11/15/05 clarified the informalities that caused the objection to claims 13, and 14. Accordingly, these objections are withdrawn. The objection to claims 27 and 28 are moot since those claims have been cancelled.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 8, 10, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al., US 5,077,049.

Dunn discloses a process for making a porous polymeric implant. The implant comprises biologically active agents such as growth hormones and others (col. 6, line 51 – col. 7, line 2). Combining a polymer solution with a coagulating solvent forms the porous implant. The polymer solution comprises a biocompatible polymer dissolved in a solvent. The polymer can be polyurethane, and the second solvent can be DMS or THF (col. 5, lines 7 – 51). The mixture is injected into the body where it takes on the shape of the implant site, after which the solvents permeate out of the polymeric body leaving pores.

Claim Rejections - 35 USC § 103

Claims 6, 7, 9, and 18 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Einstman et al. (US 3,492,154) in view of Helmus (US 5,447,724) and Le Noane (US 4,769,286).

Einstman teaches a process of making a porous polymeric sheet of polyurethane. The process comprises adding a second solvent to a polyurethane solution. The second solvent is a non-solvent, which gels the solution. Chloroform is taught to be the second non-solvent (Abstract, col. 5, col. 7, claim 1). Einstman also suggests that the polymer may be used in combination with biological and supporting materials (col. 1, lines 37 – 41).

Helmus discloses medical devices where a surface comprises porous polymeric compositsion holding a biologically active agent (Abstract). The device can be in the form of any implantable device, including sutures. The polymers can be those of instant claims (col. 2, lines 15 – 65).

La Noane teaches reinforcing materials, which may be fibers, beads, rings or others. The devices using these materials comprise the porous polymers of instant claims (Abstract, claims).

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to combine the teachings of Einstman regarding how to make porous polymers with the devices of Helmus and the support structure of Le Noane. Einstman explicitly suggests medical uses for the polymeric materials, and so it would be obvious to modify Einstman according to Helmus in order to make the suggested medical devices. It would also be obvious to modify add reinforcing members to these devices, according to Le Noane, in order to increase the mechanical stability of the devices. Accordingly, the artisan would have a reasonable expectation of success of performing a method of making an implantable device consisting of a porous polymer as taught by Einstman in the forms taught by Helmus and with reinforcing materials as taught by Le Noane. With regard to instant claims requiring a specific order of addition of the active agent, the Artisan would recognize that the order of addition of this agent is merely an optimization of the process, and would add the active agent at an appropriate time in order to achieve the best result. Since changing the order of addition of reagents in a chemical process is well within the purview of the artisan, the artisan would enjoy a reasonable expectation of success.

Claims 14 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al (US 5,077,049) in view of Reischl et al (US 3,553,008).

The teachings of Dunn are discussed above.

Dunn does not teach the use of THF to dissolve the polymer.

Reischl teaches that THF is well known as a solvent to dissolve polymers, such as polyurethane.

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use THF as a solvent to dissolve the polymer of Dunn, as taught by Reischl. The motivation is that Reischl teaches that THF is a good solvent for polyurethanes. Accordingly, the skilled artisan when seeking appropriate solvents to used as polymer-dissolving solvent in the process of Dunn, would be motivated to use THF, since Reischl teaches that THF is a good solvent for polyurethanes. As such, the artisan would enjoy a reasonable expectation of success at practicing a process of making a porous polymeric body by using THF as the dissolving solvent, as taught by Reischl, and DMS as the gelling solvent, as taught by Dunn.

Conclusion

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric E. Silverman, PhD
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY

Notice of References Cited

Application/Control No.	Applicant(s)/Patent Under Reexamination	
10/010,304	RINGEISEN, TIMOTHY	
Examiner	Art Unit	Page 1 of 1
Eric E. Silverman, PhD	1615	

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-3,553,008	01-1971	Reischl et al.	427/246
*	B	US-3,492,154	01-1970	EINSTMAN ROBERT V	427/246
*	C	US-5,077,049	12-1991	Dunn et al.	424/426
*	D	US-5,447,724	09-1995	Helmus et al.	424/426
*	E	US-4,769,286	09-1988	Le Noane, Georges	428/372
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.